K090738

510(k) Summary
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18-June-09

JUL 27 2009

ARC Medical, Inc.
4296 Cowan Road
Tucker, GA 30084

Tel - 800-950-2720
Fax - 404-373-8385

Official Contact: Harold B. Norris - President

Proprietary or Trade Name: FilterFlo™ filter
ThermoFlo™ Filter/HME

Common/Usual Name: Bacterial filter and Heat and Moisture Exchanger

Classification Name/Code: CAH – breathing circuit / bacterial filter

Device: FilterFlo™ filter
ThermoFlo™ filter/HME

Predicate Devices: Pharma Systems – K903056 – Bact Trap filters
Pharma Systems – K903058 – Bact HME
Drager – K072002 – Care Star 30 and Twin Star 55

Device Description:
The ARC Medical filter and filter / HME are standard breathing circuit filters or filter / HMEs.

Indications for Use:
FilterFlo™ filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anesthetic or ventilator breathing systems.

The FilterFlo™ filter may either be used on the patient side or on the device side of the ventilator / anesthetic device and is used as a hygienic measure alternatively to decontamination of breathing system and / or breathing gas conveying parts of the ventilator.

The ThermoFlo™ filter/HME is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The product is the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport since heated humidified are almost impossible to use. The ThermoFlo™ filter/HME should be used with patients who have a Tidal Volume between 250 - 1500 ml.

The products mentioned above are designed as disposable single patient use and should be changed at least every 24 hours.

Patient Population: Specified by tidal volumes for the filter/HME

Environment of Use: Hospital, sub-acute institutions, and pre-hospital

The ThermoFlo™ filter/HME and FilterFlo™ filter are viewed as substantially equivalent to the predicate devices because:

Indications –

- Identical to predicate – Drager Care Star 30 and Twin Star 55 (K072002)

Technology –

- Identical technology to – ARC Medical (Pharma Systems) K903056 and K903058 and Drager (K072002)

Materials –

- The materials in patient contact have not been changed and are identical to predicate devices - ARC Medical (Pharma Systems) K903056 and K903058.

Environment of Use –

- Identical to predicate – ARC Medical (Pharma Systems) K903056 and K903058

Comparative Performance Testing –

- We have performed comparative performance testing between the proposed and predicate devices. The tests included – BFE / VFE Filtration testing, resistance to flow, internal volume, HME performance.
- We found that the performances were substantially equivalent.

Differences –

There are no differences between the predicates and the proposed device. We are only changing the indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ARC Medical, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

JUL 27 2009

Re: K090738
Trade/Device Name: ThermoFlo™ Filter/HME, FilterFlo™ Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: June 18, 2009
Received: June 30, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

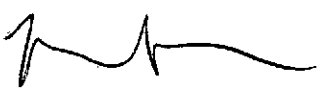
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K090738

Device Name: ThermoFlo™ filter/HME
FilterFlo™ filter

Indications for Use:

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Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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